HFC-35 3/16/98

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

d1470b
PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4390

98-PHI-15

WARNING LETTER

February 27, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

GEN. SPEC.
RELEASE
F# _____ DATE 3/3/98
Reviewed by: Wm. W. Knipe

Mr. Ronald Schad, President
Women's Mobile Diagnostic, Ltd.
360 Gardner St.
Philadelphia, PA 19116

Inspection ID: T00056T66
MQSA Facility ID: 219303

Dear Mr. Schad:

On January 7, 1998, your facility was inspected by representatives of the Food and Drug Administration (FDA), pursuant to the Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. §263b(g)). This inspection revealed a serious regulatory problem involving the mammography operations at your facility.

Under MQSA, a United States Federal law, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The findings identified during the January 7, 1998 inspection indicate that conditions exist at your facility that could compromise the quality of mammography and that specific steps must be taken to correct the violations.

The specific problems identified below were, among others, included in your MQSA Facility Inspection Report (Inspection ID: T00056T66) (Enclosure 1), which was finalized on January 23, 1998 and transmitted to you via facsimile on that date. **These problems are considered Level 2 repeat findings because the two problems were previously identified during the April 22, May 20 and 29, and June 2, 1997 inspection of your mobile mammography facility, under MQSA Facility ID# 154054. A** Warning Letter, dated June 16, 1997, was sent to you regarding these and other findings **(Enclosure 2).**

The January 7, 1998 inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, including:

- Quality Assurance/Quality Control - Equipment
[21 CFR 900.12(d)(1)(i)]

Thirty-five (35) percent of the data points for medium density (MD), density difference (DD), and base+fog (B+F) were missing for the month of October 1997 for the [redacted] processor.

- Quality Assurance - Clinical Image Interpretation/Medical Audit
[21 CFR 900.12(d)(4)]

There was no medical audit system in place to track positive mammograms.

In addition to the Level 2 repeat findings cited above, the following Level 2 and Level 3 findings were identified:

Level 2 Findings

- Quality Assurance - Equipment/Dark Room Fog
[21 CFR 900.12(d)(1)(i)]

The measured darkroom fog level of 0.10 exceeded the maximum allowable level of 0.05.

- Personnel - Radiological Technologist
[21 CFR 900.12(a)(2)(v)]

The radiologic technologists [redacted] and [redacted], did not have documentation demonstrating the accumulation of the minimum of 15 continuing education credits in mammography over a three year period.

Level 3 Findings

- Quality Assurance/Quality Control - Equipment
[21 CFR 900.12(d)(1)(i)]

There were no compression test quality control (QC) records present for the [redacted] unit.

- Quality Assurance/Quality Control - Equipment
[21 CFR 900.12(d)(1)(i)]

Corrective action was indicated on the QC records for the Screen Film Contact test, but the execution of corrective action was either not taken or not documented on at least one occasion.

Further, our review of the medical physicist's report revealed that the sum of the anterior side and chest side deviations for the x-ray field/light field collimation test for the 24cm x 30cm cassette was 4.8% of the SID, which exceeds the 2% action limit stated in the survey report. However, the medical physicist's report did not include a recommendation for corrective action.

We have reviewed the Level 3 findings identified as numbers 9, 10, and 11 on your inspection report and have determined that these items are considered acceptable within current FDA policy guidelines and, therefore, will be deleted from the inspection report.

On February 10, 1998, we received an undated, unsigned package of documents through the mail which were identified as corrective actions taken by your facility to correct the two Level 2 repeat findings and the three Level 2 findings. The following summarizes our review of your response:

Level 2 Repeat Findings:

- Quality Assurance/Quality Control - Equipment

  Thirty-five (35) percent of the data points for medium density (MD), density difference (DD), and base+fog (B+F) were missing for the month of October for the [redacted] processor.

  Your response is not adequate.

  Our review of your mammography logs revealed that mammography exams were taken on the following days during the month of October 1997: 4, 6, 7, 8, 14, 15, 18, 20, 21, 25, 27, 28, 29, and 31. Our review of your processor QC charts revealed that the processor QC was performed on the following dates in October 1997: 6, 7, 8, 13, 15, 16, 20, 21, 22, 27, 28, 29, and 30. Therefore, processor QC was not performed on the following days when mammography was performed in October 1997: 4, 14, 18, 25, and 31. The dates of October 4, 18, and 25, 1997 were Saturdays, October 14, 1997 was a Tuesday and October 31, 1997 was a Friday. You stated in your response that the days with missing processor QC were all Saturdays and that these films were processed on the following Monday. This is not correct as October 14, 1997 and October 31, 1997 were not Saturdays. You also stated that you will discontinue this practice and that all films will be processed at the end of the day.

  Action Item:
  Please send us a copy of your written procedures for performing processor QC describing the step by step procedures for performing processor QC, criteria for acceptable processor performance, corrective action to be taken if the processor is "out of limits," and instructions that processor QC will be performed on all days mammograms are taken and before exams are processed.

- Quality Assurance - Clinical Image Interpretation/Medical Audit

  There was no medical audit system in place to track positive mammograms.

  Your response is not adequate.

Under MQSA, "positive" mammograms are those mammograms interpreted as suspicious for cancer, probably cancer, or suggestive of cancer and biopsy is recommended. Each facility is required to have a system or procedure for tracking and reviewing positive mammograms and correlating them with biopsy results. The minimum biopsy data obtained should indicate if the specimen was benign or malignant. You must make a "good faith" effort to obtain the results of the biopsy exams. If you are unable to obtain the results, you should document your efforts to obtain the results, such as phone calls made and letters sent.

Under MQSA, other mammography examinations resulting in a request for an ultrasound or a 3 to 6 month follow-up are not defined as positive examinations and are not required to be tracked for purposes of the medical audit.

Action Item:
Please send us a description of your facility's system for follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports. The system should include:

1. Criteria for a positive exam.
2. Procedure to determine which mammograms are positive exams and what log system will be used to track these exams.
3. Use of the patient release form.
4. The frequency of when biopsy results will be requested for those exams entered into your positive exam log.
5. Guidance that all positive exams must be tracked regardless of where the biopsy is performed.

Additionally, your response package also included a one-page form entitled "Recommend Biopsies & Follow up" that contained a list of 15 patient names and dates. The handwritten notation "MCHD" appears above the patient names. Please provide an explanation of what the term means. Please identify what the columns numbered 1, 2, 3 and 4 are used for. It is unclear whether this list represented all positive mammography examinations identified since the facility began performing mammography. If the list does not represent all of the positive mammography examinations, please send us a copy of the complete list.

Level 2 Findings

- Quality Assurance - Equipment/Dark Room Fog

The measured darkroom fog level of 0.10 exceeded the maximum allowable level of 0.05.

Your response is adequate.

We acknowledge that you have resolved the darkroom fog problem by permanently attaching a light blocking strip on the bottom of the darkroom door.

Personnel - Radiological Technologist

The radiologic technologists, [redacted] and [redacted] did not have documentation demonstrating that they met the continuing education requirement of having completed a minimum of 15 continuing education units (CEUs) in mammography over a three year period.

Your response is not adequate.

[redacted]

You stated that [redacted] maiden name was [redacted] and that she earned 24.5 CEUs plus 24 registry exam credits in 1995 and 5 credits in 1997. Documentation substantiating the CEUs was neither included with your response nor were any observed during the inspection under either name, [redacted]

Action Item:
Please provide documentation demonstrating that [redacted]) accumulated at least 15 CEUs obtained in mammography during the three year period before the date of the inspection.

[redacted]

Your response included CEU documentation for the following:

Date	Title	CEUs Earned
10/28/95	Quality Control in Mammography	1
10/28/95	Medical Oncologist's Role in Management of Breast Cancer	1
10/28/95	Mammogram Patients Who Need Special Attention	1
10/28/95	Mammographic & Ultrasound Correlation	1
10/28/95	Surgical Approaches to Breast Masses	1
10/28/95	Positioning for Mammography	1
11/5/96	Educational Reviews, Inc*	2
	TOTAL CEUs	8

* The summary, dated 11/5/96, and agenda indicate that only issues 10 and 11 of the Program, Vol. 18, were mammography related. Therefore, only 2 of 4 CEUs are presumed to be mammography related.

We reviewed an additional CEU certificate, dated 10/28/95, for "Correlations of Pathology and Mammographic Examinations" for 1 CEU. However, the name of the participant was not legible.

Action Item:
Please provide documentation to substantiate an additional 7 CEUs in mammography (6 CEUs, if another copy of the "Correlations" certificate or other documentation can be provided) for [redacted]

In summary, it is necessary for you to act on this Warning Letter immediately. Please provide your written response to this office in writing within fifteen (15) working days from the date you received this letter. Your response should include the following:

- the specific steps you have taken to correct all of the violations noted in this letter;
- information or documentation requested as Action Items;
- each step your facility is taking to prevent the recurrence of similar violations;
- description of the corrective actions you have taken to correct the Level 3 findings; and
- copies of written procedures, quality control records or other requested records.

Please submit your written response to:

Robert E. Davis
Mammography Specialist
U.S. Food & Drug Administration
7 Parkway Center, Room 390
Pittsburgh, Pennsylvania 15220

We are concerned about your facility's inadequate response to the June 16, 1997 Warning Letter and our requests for additional information in our subsequent follow up correspondence. If you have more specific questions about mammography facility requirements, or about the contents of this letter, please feel free to contact Mr. Robert Davis, Mammography Specialist, at 412-644-3394.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/dmqrp.html.

Sincerely yours,

Diana Kolaitis
District Director
Philadelphia District

Enclosures
1. MQSA Facility Inspection Report (Inspection ID: T00056T66)
2. Warning Letter - June 16, 1997

cc: Pamela A. Wilcox-Buchalla, R.N., M.B.A.
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bcc: [redacted]
HFI-35 (redacted copy for public display)